

EXHIBIT 1

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2 IN THE UNITED STATES DISTRICT COURT
3 FOR THE NORTHERN DISTRICT OF OHIO
4 EASTERN DIVISION

5 -----X

IN RE: NATIONAL PRESCRIPTION MDL No. 2804
6 OPIATE LITIGATION,

Case No. 17-MD-2804

7 This document relates to:

8 All Cases Hon. Dan A. Polster

9 -----X

10 * HIGHLY CONFIDENTIAL *

11 * SUBJECT TO FURTHER CONFIDENTIALITY REVIEW *

12 VIDEOTAPED DEPOSITION

13 OF

14 LACEY R. KELLER

15 New York, New York

16 Thursday, June 13, 2019

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Reported by:

24 ANNETTE ARLEQUIN, CCR, RPR, CRR, RSA

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June 13, 2019

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9:10 a.m.

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HIGHLY CONFIDENTIAL - SUBJECT TO

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FURTHER CONFIDENTIALITY REVIEW

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videotaped deposition of LACEY R.

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KELLER, held at the offices of

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KIRKLAND & ELLIS LLP, 601 Lexington

13

Avenue, New York, New York, pursuant to

14

Notice, before Annette Arlequin, a

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Certified Court Reporter, a Registered

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Professional Reporter, a Realtime

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Systems Administrator, a Certified

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Realtime Reporter, and a Notary Public

19

of the State of New York and New

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Jersey.

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DAN LAWLOR, Golkow, Legal Video Specialist

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IT IS HEREBY STIPULATED AND
AGREED by and between the attorneys for
the respective parties herein, that
filing and sealing be and the same are
hereby waived;

IT IS FURTHER STIPULATED AND
AGREED that all objections, except as
to the form of the question, shall be
reserved to the time of the trial;

IT IS FURTHER STIPULATED AND
AGREED that the within deposition may
be sworn to and signed before any
officer authorized to administer an
oath, with the same force and effect as
if signed and sworn to before the
Court.

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THE VIDEOGRAPHER: We are now on

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the record. My name is Vince Rosica.

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I'm a videographer for Golkow

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Litigation Services.

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Today's date is June 13, 2019,

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and the time is 9:10 a.m.

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This video deposition is being

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held in New York, New York, in the

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matter of National Prescription Opiate

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Litigation, MDL No. 2804, for the

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United States District Court for the

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Northern District of Ohio, Eastern

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Division.

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The deponent is Lacey Keller.

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Counsel will be noted on the

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stenographic record.

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The court reporter is Annette

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Arlequin and will now swear in the

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witness.

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L A C E Y R. K E L L E R, called as a

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witness, having been duly sworn by a

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Notary Public, was examined and

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testified as follows:

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THE WITNESS: I do.

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Lacey Rae Keller.

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EXAMINATION BY

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MS. LEVY:

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Q. Good morning, Ms. Keller. My

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name is Jenny Levy, and I'm an attorney

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here at Kirkland & Ellis. I represent the

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Allergan defendants in this case.

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Thank you for being here today.

11

Apologies in advance for my scratchy voice

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and sniffles. I'm feeling very under the

13

weather, so I will do my best to keep my

14

germs away from you.

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Have you ever had your deposition

16

before?

17

A. Good morning, Jenny. Thanks for

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having me. And no.

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Q. This is the first deposition

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experience you've ever had?

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A. Correct.

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Q. In the course of your work either

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at the New York Attorney General's Office

24

or previously with SEIU, did you sit in on

25

any depositions or is this the first time

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2 law, right?

3 A. I am not an expert in the law.

4 Q. And you don't intend to offer any
5 legal opinions in this case?

6 A. I do not.

7 Q. You have not ever worked in drug
8 enforcement, have you?

9 A. No, I have never worked in drug
10 enforcement.

11 Q. You are not an expert on the
12 Controlled Substances Act, are you?

13 A. That is correct, I am not an
14 expert in the Controlled Substance Act.

15 Q. You have not ever worked with the
16 DEA, have you?

17 A. I have not. I have not worked
18 with the DEA.

19 Q. And you are not an expert in DEA
20 requirements and regulations, correct?

21 A. That is correct.

22 Q. You are not an expert or don't
23 intend to offer yourself as an expert in
24 what the DEA regulations actually mean,
25 correct?

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2 A. That is correct.

3 Q. You do not intend to offer

4 yourself as an expert in what DEA

5 registrants should or are supposed to do in

6 accordance with those guidance and

7 regulations, correct?

8 A. That is correct.

9 Q. And from a big picture level, if

10 I understand your report correctly, what

11 you have done is offer -- is do analyses

12 offering 16 different metrics and

13 illustrate what the results of those

14 metrics would show at a high level.

15 Do you agree with me that that's

16 what your report does?

17 A. Yes. I didn't actually count how

18 many metrics, so I'm taking your word that

19 there are 16.

20 Q. I will represent to you that I

21 count 16. But what I'm trying to parse

22 out, I don't mean to be mysterious, is I

23 want to make sure that I understand the

24 expertise you do intend to offer and the

25 expertise you don't intend to offer.

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So as I understand your opinions,
they are opinions from a data science point
of view that say if you ran these metrics,
here's what the results would look like.

Is that a fair assessment at a
very, very high level?

MS. CONROY: Objection.

You can answer.

A. I would say that's a fair
assessment. I was asked to apply the
compliance metrics to the labeler's data,
including chargebacks and IMS, IQ, yeah.

Q. And you don't intend to offer any
opinions about which one of those metrics
is the right one, do you?

A. That is correct. I don't endorse
any of the metrics or not endorse.
Agnostic would be the correct term, yeah.

Q. Okay. And you're not going to
offer any opinions that a particular
registrant should have or is required to
employ which ones of the metrics? That is
not what you were retained to do, correct?

A. That is correct.

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2 Q. And that is beyond your expertise
3 to do.

4 Do you agree with that?

5 A. That is correct.

6 Q. And I think, if I'm reading your
7 report correctly, you don't take any
8 opinion as to what the DEA or the
9 Controlled Substances Act means when it
10 talks about suspicious orders.

11 You are not taking a position as
12 to what specifically the DEA means, right?

13 A. Yes, I believe that's right.

14 Q. And I think it can make our day
15 easier if I understand the scope of this.

16 What you have done is you've used
17 a number of different metrics to show that
18 if a particular defendant had looked at the
19 data this way, this is what that defendant
20 would have seen.

21 Is that fair?

22 A. Yes.

23 Q. And when you use the term
24 "suspicious," which you do quite a number
25 of times in your report, what you mean by

1

2 that is the result of your own metrics,
3 right?

4 A. Yes, you can characterize it that
5 way.

6 Q. You don't mean to use
7 "suspicious" as a technical term meaning
8 suspicious under the Controlled Substances
9 Act, right?

10 MR. LEDLIE: Object to the form.

11 You can answer.

12 A. Yes, when I say "suspicious," I
13 mean that they have either triggered one of
14 the metrics, which are -- I'll leave it at
15 that.

16 Q. Okay. And you haven't, you
17 haven't gone -- have you ever met with
18 anyone from DEA about this case and your
19 report?

20 A. I have not met with anyone about
21 this case or my report from the DEA.

22 Q. Okay. Why do you hesitate?

23 A. I have spoken to DEA officials
24 about the ARCOS data and how to process it,
25 but clarifying questions of what does an S

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2 labeler impact, in your own words, you
3 phrase it as a hypothetical, right?

4 A. Correct.

5 Q. You aren't suggesting -- the
6 defendant that's subject to the small
7 labeler impact is Janssen, correct?

8 A. Yes, I believe so.

9 Q. And what you do in that section
10 is you model, hypothetically, if Janssen
11 had looked at the data this way, then
12 hypothetically, orders could have been
13 stopped, right?

14 A. That is correct.

15 Q. But you do not go further in this
16 report to opine that Janssen had an
17 obligation to do that or should have done
18 that or that the DEA expected Janssen to do
19 that.

20 That's beyond your expertise,
21 right?

22 A. That is beyond, yes.

23 Q. Okay. And, also, you don't know
24 or you don't have the expertise to know --
25 you don't consider yourself an expert in

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2 DEA reporting requirements, do you?

3 A. No.

4 Q. And you don't know what triggers
5 a reporting requirement for a manufacturer?

6 A. No.

7 Q. You don't know what triggers a
8 reporting requirement for a distributor, do
9 you?

10 A. No.

11 Q. And you don't know what triggers
12 reporting requirements for pharmacies?

13 A. No.

14 Q. It is beyond the scope of your
15 expertise to opine on what triggers a
16 reporting responsibility specifically?
17 That's beyond what you have been asked to
18 do here, correct?

19 A. Correct.

20 Q. And also just to make sure we
21 narrow in on what your opinions are, you
22 are not an expert in what DEA does with
23 suspicious reports? That is beyond your
24 expertise as well, right?

25 A. That is correct.

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Q. And I think there are places in your report where you talk about orders that could have been stopped. And I just want to make sure that I understand the parameters of what you intend to say about that.

When you talk about orders that could have been stopped, you mean from a data perspective hypothetically, correct?

A. Yes. I mean that the compliance metrics showed that order or that triggered that order and so, yes, it could have been stopped.

Q. So someone, somewhere could have stopped those orders?

A. Yes, they could have seen it or stopped it.

Q. But beyond what the data shows, do you have any opinions whatsoever on how that would work in the real world?

MS. CONROY: Objection.

You can answer.

A. No, I have no opinions on the real world.

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2 last person that put that, if you will, a
3 box together.

4 So I don't know how often that
5 box was created by somebody else and
6 labeled by someone else. They might always
7 be the same. But to be most correct, I
8 wanted to use the DEA's and the FDA's
9 terminology. I'm not sure which one, where
10 that term came from, but I saw that as part
11 of the data set.

12 Q. And so going back to the small
13 labeler impact, when you talk about orders
14 that could have been stopped, you did not
15 analyze how that would have happened, who
16 would have stopped the orders, who had a
17 duty to stop the orders, what would have
18 had to happen to stop the orders? You
19 didn't do any of that work, did you?

20 A. Correct.

21 Q. And you certainly don't intend to
22 opine that Janssen, in particular, should
23 have stopped those transactions. That is
24 beyond what you're saying. You're simply
25 saying it could have happened, correct?

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2 A. That is correct.

3 Q. And really, as you sit here, you
4 don't even know how Janssen or any other
5 registrant would actually stop those orders
6 in practice in the real world? That is not
7 something that you have ever studied or
8 know if it would even be possible, right?

9 A. That's correct.

10 Q. Okay. So let's go to the
11 summary. Let me mark your report as
12 Exhibit 5.

13 (Keller Exhibit 5, Expert
14 Analysis of Lacey R. Keller, not
15 Bates-stamped, marked for
16 identification, as of this date.)

17 BY MS. LEVY:

18 Q. Do you recognize what we've
19 handed you as Exhibit 5?

20 A. I do.

21 Q. What is that?

22 A. That is my report.

23 Q. How did this document spring
24 forth into the world? What -- who typed
25 it? Whose computer was it on? How did it

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2 didn't -- you were not asked to and you
3 didn't look specifically at Allergan?

4 MS. CONROY: Objection.

5 A. As far as we were presenting
6 results, let's say, ala, table 1 and 2,
7 correct.

8 Q. Now beginning on page 16 in
9 Section J, you describe your compliance
10 metric application.

11 Are you with me?

12 A. Yes.

13 Q. And you state in paragraph 51, "I
14 was instructed by counsel to apply metrics
15 derived and used by any manufacturer or
16 distributor and also to apply metrics
17 applied in enforcement actions, McKesson
18 and Masters, to all data sets to detect
19 prescribing and purchasing patterns of
20 unusual size, frequency and pattern."

21 Do you see that?

22 A. I do.

23 Q. When you say "I was instructed by
24 counsel," who does that refer to? What
25 counsel?

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You are not aware of any specific rules or regulations for a registrant on how to calculate patterns of unusual size or frequency, correct?

A. So I think, as I stated earlier, that's not my area of expertise.

Q. And you're not aware of any?

A. I wouldn't be able to say, but...

Q. Okay. The first metric that you employ is double the national average. And I'm looking now on page 17.

A. Correct.

Q. Are you with me?

And that metric, again, was one that Linda Singer asked you to do, correct?

A. Correct.

Q. And you didn't find it in any DEA regulations?

A. Correct.

Q. You are not aware of any place in the real world where this metric is used, correct?

MS. CONROY: Objection.

A. I wouldn't know for sure.

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2 I have there, that's where it would have
3 been derived from.

4 Q. And beyond that, you don't know
5 anything other than you were asked to run
6 it, correct?

7 A. Yeah, I was asked to review the
8 metric and implement it on the data.

9 Q. With respect to the Qualitest
10 Endo 25/50 percent national average, that
11 metric also came -- that metric was
12 presented to you by the attorneys as
13 something that you should run based on
14 documents that you were provided, correct?

15 A. It was either a metric that we
16 found or the attorneys provided. I
17 honestly can't remember.

18 Q. And for this metric, which was
19 it? Did you stumble across a document and
20 say, hey, we should run this? Or did the
21 attorneys provide you documents and say
22 based on these documents, we'd like for you
23 to run it as if this were the law of the
24 land?

25 MS. CONROY: Objection.

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2 A. I don't know.

3 Q. Do you have a supplemental report
4 in process?

5 A. No.

6 Q. Okay. And if your opinions
7 change in any way as a result of additional
8 analysis of the 2000 [sic] data or for any
9 other reason, we would ask that you bring
10 that to the attention of counsel.

11 A. Of course.

12 Q. Okay. Page 27 of the report,
13 paragraph 76, heading No. 1 at the top of
14 page 27.

15 Are you with me?

16 A. I am.

17 Q. It says, "Defendant access to
18 IQVIA data."

19 And then down in paragraph 78 you
20 make the statement that "Each of the
21 defendant labelers had access to IQVIA
22 XPONENT data."

23 Do you see that?

24 A. I do.

25 Q. That is an assumption that you

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2 were asked to make. You did not look at
3 each labeler and do an analysis of what
4 data each labeler had during what time
5 periods in the real world? You did not do
6 that, did you?

7 A. I would say it's a mix.

8 Q. Okay.

9 A. It was an assumption that we made
10 at the beginning of the report. But we
11 also, in part of the reliance materials
12 that are provided to you today, also
13 include dates in which we identified
14 defendant access to -- defendant labeler
15 access, I should be more specific, to the
16 IQVIA XPONENT data or purchase. I should
17 say purchase, not access.

18 Q. So let's go through on page 28 in
19 table 6.

20 For Endo, did you an analysis of
21 what IQVIA data Endo had in its files, what
22 type of IQVIA data Endo actually had, and
23 for what years in the 20-year time period
24 that you looked at? Is that something that
25 you did?

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2 A. I would say yes.

3 Q. Okay. And what is the answer for
4 Endo?

5 A. I'd have to pull up my files to
6 look specifically.

7 Q. You don't know?

8 A. I don't remember, no.

9 Q. Okay. Do you know -- can you
10 say, as you sit here, are you going to give
11 the opinion that Endo actually had the full
12 set of IQVIA data in its files for the
13 whole 20-year period? Is that an opinion
14 you intend to offer in this case?

15 A. So I would say it's an assumption
16 of the report but not an opinion, yes.

17 Q. Okay. And so I just want to --
18 I'm not trying to be tricky. I'm looking
19 at the first statement in 78. You say,
20 "Each of the defendant labelers had access
21 to IQVIA XPONENT data."

22 What you mean by that is they
23 could have purchased that data, right?

24 A. I would say that's correct, if
25 they didn't already purchase some form of

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2 it, yes.

3 Q. And in -- some of the labelers or
4 some of the defendants in this case might
5 have purchased some data for some time
6 periods. And you do not know and did not
7 do a deep analysis of every single labeler,
8 every single time period? You didn't do a
9 look at what each labeler had in the real
10 world, right?

11 A. We had a -- we had a high level
12 review, but I couldn't write a report on
13 each labeler's access on every year, no.

14 Q. And the metrics that you run that
15 flow from the IQVIA data are based on the
16 assumption that any of these labelers could
17 have had it all, but not assuming that they
18 actually did have it all in the real world?

19 A. Yes.

20 Q. And --

21 A. When you say "it all," I would
22 say -- I want to clarify that, if you're
23 saying that the Allergan data is it all. I
24 don't know what the "all" could be from
25 IQVIA. You know, I know only what Allergan

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2 triple national average, from McKesson

3 8,000, and from common sense.

4 Each of these metrics generates a
5 different number of flags, right?

6 A. Correct.

7 Q. You do not intend to offer any
8 opinion in this case as to which one of
9 these is right. I think you've told us
10 that, correct?

11 A. Right.

12 Q. And relatedly, you don't intend
13 to offer any opinion that any particular
14 set of these prescriptions are suspicious
15 prescribing as the DEA would define it?
16 That is not what you're here to do,
17 correct?

18 A. Correct. Whenever we use the
19 word "suspicious," we mean that it tripped
20 one of the metrics.

21 Q. When you use the term
22 "suspicious," you mean flagged by your
23 metrics?

24 A. That's precisely what we mean.

25 Q. And that is all that you mean by

1

2 that?

3 A. Correct.

4 Q. And so under your metrics, in
5 table 10, we can see the number of
6 physicians in Summit and Cuyahoga County
7 who would have been flagged by the
8 compliance metrics that you use, right?

9 A. Correct.

10 Q. And depending on which metric you
11 use, your metrics would generate thousands
12 and thousands of physicians in these two
13 counties who get flags, right?

14 A. I would say they're not my
15 metrics, but by applying these metrics,
16 yes, you would have.

17 Q. And I think I know the answer
18 now, but you are not suggesting that there
19 are actually, looking at the first row,
20 4,207 family or general physicians in
21 Summit and Cuyahoga County that are
22 actually prescribing suspiciously? That is
23 not what you mean to suggest here, correct?

24 A. Correct. What I mean to say is
25 that they were -- they tripped one of the

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2 on row 15. I'm taking your math for it,
3 but it looks to be generally right. Row 11
4 and row No. 4.

5 Q. And you don't intend to offer any
6 opinion that actually in the real world,
7 these were suspicious orders or DEA would
8 consider these suspicious orders, correct?

9 A. Correct.

10 Q. Okay. And the same analysis,
11 this one in Exhibit 6 is unique to
12 Allergan.

13 Did you isolate for any other
14 labeler the exact number of chargebacks in
15 Cuyahoga and Summit County?

16 A. Where we would, like, create a
17 table like 34 for Summit and Cuyahoga, no.

18 Q. Okay. Why didn't do you that?
19 There are many other places in your report
20 that you looked specifically at Cuyahoga
21 and Summit County. Why did you not do that
22 for purposes of table 34?

23 A. Honestly, I have no idea, but
24 it's easy to run and could be done no
25 problem, and I'd be happy to do that for

1

2 of these and two they hit on any flag.

3 Is that a correct reading of this
4 table?

5 A. Correct.

6 Q. And again, I think you've now
7 said this many, many times, but it's not --
8 you do not intend to offer any opinion that
9 these are, in fact, suspicious orders or
10 suspicious purchases by buyers. That is
11 beyond what you are able to do and beyond
12 your expertise, correct?

13 MS. CONROY: Objection.

14 A. Correct.

15 Q. And that's true for Allergan, but
16 also all of the other labelers on the
17 left-hand column?

18 A. I would say so, yes.

19 Q. Okay. And the same with table 39
20 and the dosage units, I think generally the
21 same thing applies.

22 The number of flagged dosage unit
23 changes, depending on which one of your
24 metrics are applied, correct?

25 A. Correct.

1

2 employed, right?

3 MS. CONROY: Objection.

4 A. Yes, I think that's a correct
5 characterization.

6 Q. And your analysis does not
7 include, for example, an analysis of
8 Allergan and a look at every single order
9 that it did investigate.

10 You didn't conduct such an
11 analysis for Allergan or any other labeler,
12 correct?

13 A. Let me think about that for a
14 second just to make sure I'm clear.

15 I was... I think that is correct.
16 I didn't look at the practices, I didn't
17 evaluate the practices of Allergan. I
18 didn't look at how each process was -- how
19 each order was processed, monitored,
20 flagged, unflagged or released, et cetera.

21 Q. And to be clear, you had some
22 information about suspicious order
23 monitoring programs for the various
24 labelers. You had some information, but
25 you didn't do an analysis of which ones of

1

2 the orders were investigated versus weren't
3 investigated.

4 That was beyond what you did,
5 right?

6 A. I think -- I think that's
7 correct.

8 Q. Yeah, I'm not trying to be
9 tricky. I just want to make sure.

10 You never looked at for any of
11 the flags that came up for any of your
12 metrics in the real world whether a labeler
13 actually did investigate those particular
14 transactions? That, you never looked at,
15 right?

16 MS. CONROY: Objection.

17 A. I think that's correct. I did
18 have access to the Mallinckrodt peculiar
19 orders data, but I didn't go as far as
20 beyond looking at that data set.

21 Q. And so for the set of
22 transactions that are flagged under
23 different matrices, you can't say which
24 ones of those actually got investigated,
25 which ones didn't, which ones were

1

2 legitimate, which ones weren't legitimate?

3 That is not something that you did in

4 connection with your work in this case,

5 right?

6 A. Yes, I would not be able to state

7 which ones were legitimate or not.

8 Q. Okay. And the extension of that

9 is, you have no opinion, you cannot opine

10 on what the impact would have been if a

11 labeler had investigated because you don't

12 know what those investigations would have

13 found, what would have happened after that,

14 correct?

15 A. Yes, I think we've covered this

16 one earlier, but with the exception of the

17 hypothetical Janssen analysis, that is a

18 correct statement.

19 Q. Okay. I forgot to talk to you

20 about your addendum. You provided an

21 addendum to your expert report.

22 Do you know what I'm talking

23 about when I say the addendum?

24 A. Yes, I do.

25 Q. So how did this addendum come

1

2 Q. Do you know what makes an order
3 reportable to the DEA as a suspicious
4 order?

5 A. No, I do not. As we discussed
6 earlier, outside of my expertise.

7 Q. Do you know whether DEA expects
8 registrants to conduct due diligence into
9 flagging orders -- into flagged orders to
10 determine whether they're actually
11 suspicious before reporting it?

12 A. Again, as discussed earlier,
13 outside of my expertise.

14 Q. Did you ever discuss whether
15 to -- strike that.

16 Did you ever discuss whether to
17 consider due diligence in running the
18 metrics that you ran?

19 A. So --

20 Q. Let me start over.

21 You said earlier that in your
22 report, if something is suspicious, you
23 mean it just was tripped by one of the
24 metrics, right?

25 A. That is correct.

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Q. And just because you used the word "suspicious" in your report, that doesn't mean it's suspicious as the DEA defines under the Controlled Substances Act, correct?

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A. That's accurate.

Q. So did you ever consider whether you should take due diligence into account in creating your definition of suspicious?

A. So I'm pausing for this because there's the addendum that does the persistent flagging which assumes no due diligence because once the flag is triggered, it stays on for the perpetuity of the data set.

So in the sphere that is around that, then, yes. And if we're talking about anything outside of that, then no.

Q. Are you aware whether -- strike that.

Did you look at any documents or deposition testimony regarding Janssen's due diligence of flagged orders?

A. I might have read a document or

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2 But I don't believe that we had a Janssen
3 algorithm.

4 Q. I'll represent to you we haven't
5 found one.

6 Why is it that you didn't use
7 Janssen's suspicious order monitoring
8 algorithm or compliance metric in your
9 report?

10 A. If it's not here, then, which I
11 don't think it is, I didn't know of it. So
12 if there was one, I'd be happy to implement
13 it.

14 Q. How did you choose the compliance
15 metrics that got included in the report?

16 A. As we were stating earlier, some
17 were provided by counsel, others we found.

18 Q. So there was no instruction by
19 anyone to make sure you included all of the
20 defendants' algorithms in your report?

21 A. Well, I would say that's correct,
22 there was no explicit instruction to
23 include all or exclude all, include what
24 you could find and go from there.

25 Q.. Is it your understanding that

1

2 nobody could find Janssen's suspicious
3 order monitoring algorithm?

4 A. I just wanted to look at one
5 thing really quick.

6 (Document review.)

7 Q. What page are you on?

8 A. I'm trying to find it. I'm
9 sorry.

10 Q. Are you looking for the metrics?

11 A. Yeah. I'm looking actually for
12 the footnote about Janssen that describes
13 the SOMS program.

14 (Document review.)

15 A. Because as I understood it, there
16 wasn't one to implement. But I just...
17 that's what I wanted to review.

18 (Document review.)

19 A. So, yes, it was my understanding
20 that there wasn't a metric.

21 Q. It was your understanding?

22 A. Correct.

23 Q. Did you ask anybody to confirm
24 that?

25 A. I did.

1

2 Q. Who did you ask?

3 A. Evan Janush, I think is his last
4 name. J-a-n-u s-h.

5 Q. And your understanding is that
6 Mr. Janush told you that Janssen did not
7 have a suspicious order monitoring
8 compliance metric or algorithm?

9 A. Correct, that we could implement,
10 yes.

11 Q. Did you find that footnote?

12 A. Yes. I was on page 28 here.
13 Footnote 83 is what I was looking for just
14 to make sure.

15 Q. And footnote 83 says, "Janssen
16 used chargeback and value track data on
17 occasion for size only."

18 Is that what you were thinking
19 of?

20 A. That is exactly what I was
21 thinking of.

22 Q. And what makes you think that
23 that supports the notion that Janssen did
24 not have a suspicious order monitoring
25 algorithm?

1

2 that it exists.

3 MS. LUCAS: I think Mr. Janush
4 knows about our -- Janssen's algorithm.

5 BY MS. LUCAS:

6 Q. So I wanted to talk about your
7 small labeler opinion.

8 And that applies only to Janssen,
9 correct?

10 A. That is correct.

11 Q. And why is that?

12 A. So small labeler, I don't mean
13 any offense to that because I understand
14 Johnson & Johnson is a very large company,
15 but when it comes to opioids, you have very
16 few as it pertains to the market share,
17 right? You're a much lower market share.

18 Q. Actually, if you want to turn
19 really quickly to page --

20 A. 16 you're probably looking for.

21 Q. I am.

22 Page 16, table 1 and table 2.

23 That reflects Janssen's market share in
24 Summit County and Cuyahoga County, correct?

25 A. Yes.

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Q. And the largest percentage on that table is 0.9 percent, and the smallest one is 0.1 percent, correct?

A. That appears to be correct.

Q. Did you calculate those numbers?

A. I didn't do it by hand, but an algorithm did.

Q. How did you do that?

A. SQL query.

Q. And you concluded that Janssen had between 0.1 percent and 0.9 percent market share in Summit and Cuyahoga, correct?

A. Yes, depending on the metric and depending on the county.

Q. And other manufacturers, either defendants or otherwise not named in the complaints, had between 99.1 and 99.9 percent of the market share, correct?

A. Yes. I'm assuming you're taking the hundred minus yourselves and that's everybody else, yes.

Q. So then back to your small labeler opinion, why then did you conduct

1

2 A. I believe so, yes. I'd have to
3 look at the code to be for certain.

4 Q. So in order for this analysis to
5 work, you had to assume that the prescriber
6 was taken off-line the moment the metrics
7 used were tripped and there was a flag,
8 correct?

9 MS. CONROY: Objection.

10 A. I would say for this hypothetical
11 situation to present itself, yes, once
12 someone was flagged and they were taken
13 off-line, what their, what amount of
14 prescriptions were then taken off-line.

15 I'm trying to say it the best way
16 I can. I'm sorry if I'm not being clear.

17 Q. Do you believe that your small
18 labeler impact opinion is an accurate
19 representation of what happens in the real
20 world?

21 A. I'm not really an expert to say
22 that.

23 Q. Do you have any beliefs on
24 whether it's an accurate representation of
25 what would happen in the real world?

1

2 your opinion of what would happen?

3 A. So I would say that the change
4 that we made earlier in the corrections
5 where we went from "would" to "could,"
6 those should have been throughout. I
7 didn't really get to talk about every
8 single change here. But, again, these are
9 "could" statements, and I think we stated
10 that pretty definitively in the first part
11 of this deposition.

12 Q. Right. I asked because I noticed
13 that the corrections didn't apply to this
14 paragraph. And so you are now saying that
15 you meant to say "could" have happened?

16 A. I would be most comfortable with
17 saying "could."

18 Q. And "could" means that it's
19 feasible, correct?

20 A. I think that's what that word
21 means, yes.

22 Q. Do you believe that your small
23 labeler impact opinion is feasible in the
24 real world?

25 A. I'm not here -- I won't talk

1

2 about real world. It's outside of my
3 expertise.

4 Q. So you're not offering any
5 opinion about whether your small labeler
6 impact opinion could happen in the real
7 world, right?

8 MS. CONROY: Objection.

9 A. So I think we've said here that
10 this was what could happen. I'm not
11 offering an opinion about what would happen
12 or should happen.

13 Q. Right.

14 But you're also not offering an
15 opinion about what could happen as applied
16 in the real world, right?

17 A. I guess I'm not really
18 understanding the difference between that
19 question and the one that I just answered.

20 Q. Well, because you said this is
21 all hypothetical.

22 A. Sure, but it relies on real-world
23 data.

24 Q. Which data?

25 A. The IQVIA data.

1

2 Q. It is then your opinion that this
3 could happen in the real world, correct?

4 A. It seems a little... it's a lot
5 of time to spend on a hypothetical, but,
6 yes, if all of the assumptions that were
7 outlined in the report that the labeler was
8 -- or that the labeler identified the
9 prescriber and that all the different steps
10 were taken to take them off-line, then,
11 yes, it could happen in the real world.

12 Q. Well, the only two assumptions I
13 think I heard were that one of the metrics
14 was tripped and a flag went up, correct?

15 A. That is one part of the
16 hypothetical.

17 Q. And Janssen would report that
18 prescriber to law enforcement as
19 suspicious, right?

20 A. So as part of the hypothetical,
21 they would be tripped, Janssen could report
22 them. That prescriber, through whatever --
23 or they could be reported, or they could
24 stop prescribing, whatever the means are to
25 get them to stop prescribing.

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2

But the whole point of the

3

analysis is that that prescriber who was

4

flagged then stops prescribing. I don't

5

really claim or really fill out the blanks

6

between what gets from A to B.

7

Q. You said that your assumption is

8

that the prescriber would stop prescribing

9

immediately upon the metric being tripped,

10

right?

11

A. Correct.

12

Q. Do you have any basis to believe

13

that those assumptions would happen in the

14

real world?

15

A. It's really outside of my

16

expertise.

17

Q. You don't know?

18

A. I don't know.

19

Q. Have you ever thought when you

20

were thinking about this analysis whether

21

it was flawed?

22

MS. CONROY: Objection.

23

A. I think --

24

MS. CONROY: Which analysis? The

25

hypothetical you're talking about or --

1

2 only the algorithm?

3 A. Yes, I think that would be a
4 better characterization.

5 Q. So you're excluding from
6 suspicious order monitoring program, any
7 follow-up due diligence that the suspicious
8 order monitoring department did when an
9 order was flagged, right?

10 MS. CONROY: Objection.

11 A. Yeah, I would say that's outside
12 of the scope. So to the extent that there
13 was an algorithm that we could implement
14 and chargebacks were used as part of that
15 algorithm, then they get the "yes" here.

16 Q. Got it.

17 And so...

18 (Document review.)

19 Q. All right. Take a look at page 4
20 of the --

21 MS. LUCAS: Do we have the errata
22 sheet marked?

23 MS. CONROY: Yes.

24 MS. LUCAS: From 5/11?

25 Has this been marked?

1

2 appeared in the chargeback data.

3

4 Q. And for seven of them, you say
5 that seven were flagged by any metric,
6 correct?

7

8 A. Sorry, just a second. I just
9 want to make sure.

10

11 So your question earlier, it says
12 total buyers, 12. Yes, total buyers in the
13 chargeback data. And then seven of which
14 were flagged by any metric.

15

16 Q. Did you do any research yourself
17 to determine whether any of those buyers
18 were actually suspicious?

19

20 MS. CONROY: Objection.
21 A. That would be outside of the
22 scope of my expertise.

23

24 Q. And if you take a look back at
25 your report in Exhibit 5 at page 28, table
26 6, this is about IQVIA data.

27

28 I want to confirm what I think is
29 going to be the case based on what you just
30 told me.

31

32 In paragraph 80, it says,
33 "Janssen discusses using IQVIA data for

1

2 looking for it.

3 Q. Well, I guess I'm trying to
4 understand why this opinion exists if you
5 can't tell me that there is any evidence in
6 the record that it reflects things that
7 actually happened.

8 A. I mean, it was a hypothetical
9 request by -- to me, and so that's what I
10 enacted. I was asked to enact that.

11 Q. Quickly, you said that your
12 opinion assumes that the doctor would stop
13 prescribing immediately upon being reported
14 to law enforcement, correct?

15 MS. CONROY: Objection.

16 A. I would say the assumption is
17 that they do not have any more
18 prescriptions. However that comes to be
19 is...

20 Q. But do you know how long
21 investigations into prescribers take?

22 A. Outside of my expertise.

23 Q. Well, if you look at page 40 of
24 your report, on paragraph 96, it's talking
25 about a prescriber named Ronald Celeste.

1

2 And there was an "...uptick in
3 prescriptions caught the attention of the
4 authorities, who launched a two-year
5 investigation into his practice in 2014."

6 So you know here, in your report,
7 is that the investigation into Mr. Celeste
8 lasted two years, correct?

9 A. That was what was reported in the
10 news.

11 Q. And that's in your report, right?

12 A. It is, but it's one
13 investigation. I can't say what's typical
14 length of time for an investigation. It's
15 outside of my expertise.

16 Q. Yes or no, are you aware of any
17 instance ever in the real world where a
18 prescriber stopped prescribing the moment
19 that an investigation was opened into him
20 or her?

21 MS. CONROY: Objection.

22 A. I'm not really here to talk about
23 the real world. It's outside of my
24 expertise, so I can't answer a "yes" or
25 "no" to that.

1

2

Q. Well, that's not my question.

3

I'm asking you if are aware of any instance

4

in the real world where a prescriber ever

5

stopped prescribing the moment an

6

investigation was opened.

7

A. Again outside of my expertise, so

8

I can't speak to something that I know or

9

don't know.

10

Q. You don't know what you don't

11

know?

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A. Actually, I don't know what I

13

don't know?

14

Q. I mean, I'm -- you're avoiding my

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question because my question is pretty

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simple.

17

It's are you aware of any

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instance where a prescriber stopped

19

prescribing the minute that an

20

investigation was opened into his or her

21

prescribing practices?

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MS. CONROY: Objection.

23

BY MS. LUCAS:

24

Q. Do you know of that, yes or no?

25

A. I just am not going to answer a

1

2 question about something that's not my area
3 of expertise.

4 Q. Well, refusing to answer
5 something and not knowing are different
6 things.

7 Is it then correct that you don't
8 know of any instance where a prescriber
9 stopped prescribing the minute that an
10 investigation was opened into his or her
11 prescribing practices?

12 A. Look, I haven't looked at that.
13 It's not part of my expertise. I would not
14 know because it's not part of my expertise.

15 Q. But you're offering an expert
16 opinion on this fact that assumes this.
17 And in order to offer this opinion, you
18 have to have some factual basis for it.

19 So do you have a factual basis
20 for this opinion or not?

21 MS. CONROY: Objection.

22 A. So what I'm offering is a
23 hypothetical scenario using the data that's
24 been provided to me. I have no expertise
25 in the real world, due diligence, et

1

2 cetera, that goes beyond that. So there's
3 a set of assumptions that go into this and
4 that is all.

5 Q. So in order for you to get on the
6 stand and testify about this opinion at
7 trial, you must identify a factual basis.

8 Can you do that today?

9 MS. CONROY: Objection.

10 A. I really don't know what will go
11 into that and so I can't answer that.

12 Q. Is one of the other assumptions
13 in your small labeler impact analysis that
14 the patient who would have gotten the
15 prescription of the flagged doctor does not
16 go to another doctor and get that same
17 prescription?

18 A. I wouldn't say that we talk about
19 anything about patients in this report.

20 Q. You didn't consider that?

21 A. That was not something I would
22 consider as part of this set of
23 assumptions. The patients are not
24 considered in really anywhere in this
25 report.

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Q. And you didn't consider also whether or not whether the medical board would revoke prescribing privileges immediately, correct?

A. Again, it was not part of the assumptions yes or no. It's just we had too make the assumption -- to do the analysis, you make the assumption that the prescriber stopped prescribing. The steps between medical board, due diligence, et cetera...

Q. Right. Because it doesn't work unless you assume that the prescriber stopped prescribing immediately, correct?

A. I wouldn't characterize it as it doesn't work. It's just part of the exercise.

Q. Well, does it work if the prescriber didn't stop prescribing immediately? Does the result stay the same?

A. So you could create a period of which time -- you know, you could say give them six months after which they were first

1

2 flagged and implement that. It's an
3 analysis. How I complete the analysis can
4 work -- you can bake in any amount of time
5 you'd like, after which time they're first
6 flagged if that's --

7 Q. But for this --

8 A. -- part of this.

9 Q. Sorry.

10 A. Yes, but for this, that was not
11 part assumption.

12 MS. LUCAS: I will reserve my
13 rights given the time constraints and
14 that I have a few more questions or
15 many more questions. If I were given
16 the time, we could spend much more time
17 together, but subject to that
18 Reservation of Rights, we are done and
19 I will pass the witness.

20 Can we go off the record for just
21 a moment?

22 THE VIDEOGRAPHER: The time is
23 3:42 p.m. We are now off the record.

24 (Recess is taken.)

25 THE VIDEOGRAPHER: The time is

1

2 Mr. Buthusiem writes, "Across the
3 pharmaceutical industry, chargeback
4 requests from distributors to manufacturers
5 do not indicate what specific product
6 inventory, i.e. which particular bottles or
7 packages, the distributor used to fulfill
8 the sale to the downstream registrant."

9 Do you see that?

10 A. I do.

11 Q. Do you agree with that statement?

12 A. I really wouldn't know. It's
13 outside of my expertise.

14 Q. So you have no reason to disagree
15 with that statement?

16 A. I wouldn't have the expertise to
17 agree or disagree.

18 Q. Okay. Skipping down to the
19 sentence in the middle of the paragraph
20 that starts "As such," do you see that?

21 A. I do.

22 Q. And the underlying portion reads.
23 "The manufacturer cannot use chargeback
24 data to trace a downstream sale back to the
25 specific original direct manufacturer to

1

2 distributor sale or sales."

3

Do you see that?

4

A. I do see that.

5

Q. And do you agree with that

6

statement?

7

A. I do not.

8

Q. Which part do you disagree with?

9

A. Which part? I'm sorry. Ask me a

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different question or --

11

Q. Sure.

12

What do you disagree with about

13

that statement?

14

A. So I believe in my report we do

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trace the chargeback data back to the --

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for a second.

17

So he refers to sales data. I

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didn't review sales data. So I actually

19

couldn't be certain if you could trace a

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chargeback back to sales data.

21

What I had available to me was

22

chargeback data and peculiar order data.

23

Q. Just so the record is clear, what

24

sales data are you referring to that

25

Mr. Buthusiem reviewed that you said you

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2 chargeback from the sale from the
3 manufacturer to a distributor and then from
4 a distributor to the distributor's
5 downstream customer.

6 Do you recall that?

7 A. So I think what I was saying is
8 because I haven't fully reviewed the sales
9 data, I don't know what would be possible.
10 So that was -- I think I started making a
11 statement but needed to clarify that.
12 Because I haven't used this direct sales
13 data and done this analysis, I don't know
14 the answer.

15 Q. Okay. At this point, you're not
16 aware of any information in the direct
17 sales data that would enable you to trace a
18 manufacturer's sale to a distributor, to
19 then a distributor's sale to a downstream
20 customer?

21 A. I'm really not prepared to answer
22 that either way right now.

23 Q. So I was just asking if you're
24 aware of any information at this point.

25 A. I just -- I've reviewed the file

1
2 fairly quickly. I'm just really not
3 prepared to say what's in the file or what
4 data points are there or what would be
5 possible to review. So I just am not
6 comfortable with saying one way or the
7 other what is possible or not possible.

8 Q. Oh, I understand. I think my
9 question is a little different.

10 It's simply, at this point in
11 time sitting here today, if you are aware
12 of any information that would enable you to
13 trace manufacture's sale to a distributor,
14 trace that order from the manufacturer to
15 the distributor to the downstream customer?

16 A. So, again, the data that I used
17 in my report was peculiar orders and
18 chargebacks. The data that's mentioned
19 here that I've only briefly reviewed is
20 sales. So I can't offer an opinion or a
21 statement at this time about sales.

22 Q. So what I'm trying to understand
23 is that based on your review thus far,
24 understanding that it's incomplete review
25 of the Mallinckrodt direct sales data, if

1

2 there's any information that you've come
3 across to date that would enable you to
4 trace the manufacturer's sale to a
5 distributor, to then the sale by the
6 distributor to a downstream customer?

7 MS. CONROY: Objection. Apart
8 from her report?

9 MR. GOLDSTEIN: Based on her
10 review of the Mallinckrodt direct sales
11 data, which is --

12 MS. CONROY: That's what you're
13 your question is about, the
14 Mallinckrodt direct --

15 MR. GOLDSTEIN: Correct.

16 MS. CONROY: Okay. Why don't you
17 ask it again, then.

18 MR. GOLDSTEIN: Correct.

19 MS. CONROY: That's what's
20 confusing.

21 MR. GOLDSTEIN: Right. So I
22 understand the testimony to be that
23 Ms. Keller can't say whether the direct
24 sales data that Mr. Buthusiem reviewed
25 would enable or would not enable

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2

someone to trace the order all the way

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from the manufacturer to the downstream

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customer. And so that's where I'm

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going with that.

6

MS. CONROY: Okay.

7

BY MR. GOLDSTEIN:

8

Q. So would you like me to repeat

9

the question?

10

A. Yes, please.

11

Q. So based on your review thus far

12

of the Mallinckrodt direct sales data that

13

Mr. Buthusiem cites in his report, do you

14

have any -- are you aware of any

15

information in that data that would enable

16

you to trace a sale from a manufacturer, to

17

a distributor, to then the downstream

18

customer?

19

A. I mean, again, that is a very

20

long chain that you've outlined here. I

21

would need to fully review it to make -- to

22

make an actual assertion.

23

I mean, if there's NDC codes in

24

there, that's where we would start. But

25

beyond that, I don't -- I'm not prepared to

1

2 talk about that right now.

3

Q. So I think I've asked this
4 question about five times.

5

All I'm asking is what you're
6 aware of today, not what you could ever
7 possibly be aware of at some future point
8 down the road.

9

So as far as, as you sit here
10 today what you're aware of and not aware
11 of, it sounds like you're not aware of any
12 information that would enable you to trace
13 an order from a manufacturer, to a
14 distributor, to the downstream customer?

15

MS. CONROY: Objection.

16

A. I'm not going to say aware or not
17 aware because I haven't fully reviewed the
18 data set. If you want to pull it out, I'd
19 be happy to look at it right now, but I
20 don't remember what column headers are in
21 there. I don't know what fields are in
22 there. I just -- those are things that I
23 would need to know to be aware or not aware
24 and I just -- I would be happy to look at
25 it right now if you want to pull it up on a

1

2 computer, but...

3 Q. Sitting here today, you don't
4 recall if you're aware or not of whether
5 there is any information in that direct
6 sales data that would change your analysis?

7 A. So sitting here, I do not have
8 the familiarity with the data set that
9 would allow me to answer the question
10 either way, that I am aware or unaware,
11 because I would just have to look at the
12 data set more closely to be able to answer
13 the full question of being able to trace
14 from here to here to here.

15 Q. Okay. Well, let me move on and
16 ask a slightly different question. I think
17 everyone is growing weary of that one.

18 If you turn to your report,
19 paragraph 158. It's on page 84.

20 A. Yes.

21 Q. And there, you reference roughly
22 2,900, I think if you look at table 74,
23 it's 2,860 peculiar orders, or to be clear,
24 orders that Mallinckrodt had deemed
25 peculiar based on its own monitoring system

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2

MS. CONROY: Objection.

3

4

A. How they were shipped, like what was the method that they arrived in Summit County?

5

6

7

Q. Yes. They were shipped there by a distributor into Summit or Cuyahoga County.

8

9

Is that your opinion?

10

11

12

13

14

15

A. I guess I don't really understand the question. I'm sorry if I'm -- I'm not trying to be obstinate. I just don't understand. Are you asking me -- I just don't understand quite what you're asking me.

16

17

18

Q. What I'm getting at is that, once a, once product is shipped -- I'll start over.

19

20

21

22

23

Do you have an understanding of whether distributors that receive products from manufacturers typically hold inventory of the product that they are purchasing beyond the single order that was purchased?

24

25

A. I have no expertise in what the inventory practices are of distributors.

1

2

Q. So you don't know if, for

3

example, if a distributor purchases --

4

places an order with Mallinckrodt for one

5

of its products, you don't know if -- and

6

Mallinckrodt ships it to that distributor,

7

the product that was purchased, you don't

8

know if the distributor would have other of

9

Mallinckrodt's products already in its

10

inventory at the time it places that order?

11

A. Correct. I'm not an expert in

12

supply chain, nor am I an expert in

13

distributor LIFO or any of their practices

14

there, nor do I -- you had another point in

15

there, but, no, that would be outside of my

16

expertise. Actually, nor was I given data

17

on those practices.

18

Q. Okay. And if a distributor at

19

the time it placed an order that the

20

distributor deemed -- that that -- strike

21

that.

22

If a distributor in its inventory

23

had product from Mallinckrodt that was

24

purchased via multiple orders --

25

Are you with me so far?

1

2 that's what's stated here.

3 Q. Okay. The next sentence says,
4 "The chargeback data submitted with respect
5 to any eligible distributor to downstream
6 registrant sale does not delineate which
7 specific distributor to manufacturer order
8 relates to the chargeback."

9 Do you have any reason to
10 disagree with that statement?

11 (Document review.)

12 A. I don't understand what the word
13 "eligible" means, so I don't really know if
14 I can agree or disagree with this.

15 And it's also referencing sales
16 data that, again, we've discussed earlier
17 that I haven't reviewed fully.

18 Q. So let me break that up. I'll
19 represent to you that eligible distributor
20 to downstream registrant sale simply means
21 a sale for which a chargeback was issued.

22 A. Sure.

23 Q. A chargeback eligible sale.

24 Okay. Does that make sense?

25 A. Sure.

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Q. Okay. Now based on the data that you've reviewed to date and as you sit here today, do you have any reason to disagree with the sentence that I just read?

A. And I just assume that there is an order number, an order ID in both data sets, is there?

Q. You assume that there is an order ID in both sets of what?

A. Of both the chargeback data and the sales data. *

Q. That is the same order ID, is that what you're saying?

A. I would think that that exists.

Q. Okay. And so if that is the case -- sorry. If that is not the case, then you would not be able to delineate which specific distributor to manufacturer order relates to the chargeback?

A. I mean, I'd have to look at the data sets again to see whether or not I could trace it or not. Again, you're asking me look at data I haven't fully reviewed.

1

2 Q. Sure?

3 A. Okay.

4 Q. Chargeback data is submitted for
5 one of those orders.

6 A. Sure.

7 Q. Are you aware of any information
8 in the chargeback data that identifies
9 which order of the two orders in the
10 distributor's inventory that chargeback
11 data pertains to?

12 A. So the -- I will say what I know
13 that exists in the chargeback data. I can't
14 talk about the inventory system of the
15 distributor.

16 The chargeback has an NDC number,
17 the distributor that shipped it or that
18 submitted it, I should say, to be most
19 correct, as well as an order number and a
20 date.

21 Q. And is it your understanding that
22 the NDC code that's included pertains to
23 the product that's being shipped?

24 A. I would understand the NDC to be
25 the product, yes.

1

2 Q. And not a particular order that's
3 being shipped?

4 A. I think you could characterize
5 the NDC is part of a larger order.

6 Q. I'm not sure I follow.

7 The NDC relates to the type of
8 product that's being shipped?

9 A. So I have seen the data, have an
10 order number, let's say one, two, three,
11 four, five, have as part of it, and this is
12 a hypothetical, but I've seen real examples
13 of the data, an order for -- the same order
14 number also have oxycodone, morphine and a
15 hydrocodone product as part of that whole
16 order.

17 Q. And that's all under the same NDC
18 code?

19 A. No, different NDC codes folded
20 underneath one order.

21 Q. Okay. But understood the NDC
22 order only pertains to the product that's
23 being shipped?

24 A. Yes. I think we've talked about
25 that.

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C E R T I F I C A T E

STATE OF NEW YORK)

: ss.


COUNTY OF WESTCHESTER)

I, ANNETTE ARLEQUIN, a Notary
Public within and for the State of New
York, do hereby certify:

That LACEY R. KELLER, whose
deposition is hereinbefore set forth,
was duly sworn by me, and that the
transcript of such depositions is a
true record of the testimony given by
such witness.

I further certify that I am not
related to any of the parties to this
action by blood or marriage; and that I
am in no way interested in the outcome
of this matter.

IN WITNESS WHEREOF, I have hereunto
set my hand this 14th day of June, 2019.



ANNETTE ARLEQUIN, CCR, RPR, CRR, RSA